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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,758	09/29/2006	Yoshihiro Nomura	296946US0PCT	5292
22850 7590 10/07/2009 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER TSAY, MARSHA M				
ART UNIT		PAPER NUMBER		
1656				
NOTIFICATION DATE		DELIVERY MODE		
10/07/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/594,758

Applicant(s)

NOMURA ET AL.

Examiner

Marsha M. Tsay

Art Unit

1656

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 9-21 and 23-25 is/are rejected.
- 7) ☒ Claim(s) 8 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 31, 2009 has been entered.

Claim 6 is canceled. Claims 1-5, 7-25 are pending and currently under examination.

Priority: The request for priority to JAPAN 2004-107286, filed March 31, 2004, is acknowledged. A certified copy of the foreign priority document has been filed in this case on September 29, 2006, and is in a non-English language.

The declaration under 37 CFR 1.132 filed August 31, 2009 is insufficient to overcome the rejection of claims 1-5, 7-19 based upon Shiojima et al. (US 6066316) in view of Mullner et al. (WO 0236801 abstract) as set forth in the last Office action for the reasons noted below.

Objections and Rejections

Claims 19-20 are objected to because of the following informalities: in claim 19, there should be an "and" or a "comma" inserted between "odorless" and "which"; in claim 20 line 4, there should be a "to" inserted between "solution" and "produce." Appropriate correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Arai et al. (US 5763583; previously cited). Arai et al. teach a solubilized keratin product that is treated with an oxidizing agent, i.e. hydrogen peroxide (col. 4 lines 1-4, col. 7-8 examples 1-4; claims 9, 19). The solubilized keratin product is suitable for use in a cosmetic composition (col. 6 lines 20-24; claim 10). Arai et al. further teach that keratin can be obtained from feathers (col. 2 lines 15-20; claims 9, 19). While instant claims 9 and 19 are product-by-process claims, the product of said claims is believed to be the same as the keratin product of Arai et al. since both the instant keratin and the keratin of Arai et al. are treated with hydrogen peroxide (and would therefore be odorless and colorless) and are suitable for use in cosmetic compositions.

In their remarks, Applicants assert that claims 9 and 19 have been amended so that the claims are directed to keratin from feathers. Applicant's arguments have been fully considered but they are not persuasive.

As noted above, Arai et al. teach that the keratin can be obtained from feathers (col. 2 lines 15-20).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-21, 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiojima et al. (US 6066316; previously cited) in view of Mullner et al. (WO 0236801 abstract). Shiojima et al. disclose pretreated and/or washed keratin (i.e., hair, wool, etc.) can be hydrolyzed by alkali solutions (i.e. sodium hydroxide, potassium hydroxide) having a concentration between 1 to 20% in general (col. 22 lines 1-10, 39-40). Further, the hydrolysis reaction is conducted at room temperature to 100°C and for 30 minutes to 24 hours (col. 22 41-43). In Synthesizing Example 3(II) and (IV), Shiojima et al. disclose keratin raw material was immersed in aqueous solution, hydrolyzed in alkali solution, said keratin-alkali solution was neutralized, and filtered to obtain a keratin hydrolyzate (col. 28). Shiojima et al. also disclose that salt can be removed by a membrane step (col. 28 lines 40-41). Shiojima et al. also disclose that feathers can be used as the keratin material (col. 22 lines 5-7). Shiojima et al. do not explicitly teach a hydrous state of 20 to 80%.

Mullner et al. teach keratin protein hydrolysates obtained from keratinous waste (i.e. wool, feathers, hooves, etc.) are suitable for use in cosmetic compositions (p. 3). Mullner et al. teach that the substrate is a natural proteinaceous product preferably with a water content of 5-99 weight %, especially a substrate containing keratin (p. 4). The final keratin protein product contains substantially no toxic constituents (p. 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Shiojima et al. by substituting the keratin material (having a water content in the range of 5-99 wt %) of Mullner et al. for the raw keratin used in Shiojima et

al. (claims 1-4, 7-13, 17-21, 23-25). The motivation to do so is given by Mullner et al., which teach that using a keratinous substrate having a water content in the range of 5-99 weight % in a protein hydrolysis process can eliminate toxic constituents in the final keratin protein product and by Shiojima et al., which disclose that said keratinous substrate can be pretreated (i.e. washing) prior to said protein hydrolysis process (col. 22 lines 9-65).

Regarding the limitation of an alkali concentration of 0.1 to 0.5 mol/L (claims 3, 24), this limitation is within the range taught in the prior art. The concentration 0.1 to 0.5 mol/L is within the 1-20% of Shiojima et al. One mole of NaOH is 40 g. So, 0.5 mole is 20 g. If 20 g NaOH is dissolved in 1 L of water, the concentration of NaOH would be 0.5 mol/L or 2% (w/v) which is about what Applicants have used in their examples. If the alkali has a higher molecular weight e.g. potassium hydroxide, the percentage would be higher at the same molar concentration.

Shiojima et al. also disclose that said keratin raw material can be hydrolyzed by acidic solutions having a concentration between 3 to 85% in general (col. 22 lines 15-20). Further, said keratin raw material can be treated with hydrogen peroxide (col. 23 lines 24-34, col. 26 lines 40-41).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Shiojima et al. by using the various hydrolysis processes alone or in combination (i.e. acidic treatment and/or hydrogen peroxide treatment) for the treatment of said keratin material of Mullner et al. (having a water content in the range of 5-99 wt %) in order to obtain a solubilized keratin protein product (claims 5, 14-16, 25). Since Shiojima et al. disclose various treatment steps that can be applied to the keratin raw material, it would be reasonable for one of ordinary skill to combine and/or execute the various treatment

steps in order to obtain an optimum solubilized keratin protein product. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this instance, the normal desire of scientists to determine which steps and/or components should be included in a process for producing solubilized keratin without toxic constituents and that are suitable for use in a cosmetic compositions provides the motivation do determine the optimum working conditions.

In their response, Applicants assert (1) Mullner et al. is directed to enzymatic hydrolysis and not a process of alkaline hydrolysis as required by the instant invention. Thus, Mullner et al. could not have provided a reasonable expectation of success for the superior efficiency of the decomposition rate by alkaline hydrolysis achieved by selection of a keratin raw material having a water content ranging from 20% to 80%, especially as Mullner controls water content for an entirely different purpose, namely in order to arrange dosage form. (2) Shiojima et al. disclose alkali treatment of hydrated feathers, but it does not provide a reasonable expectation of success for the superior results achieved by selection of a hydrous state for the keratin raw material ranging from 20 to 80% as shown in table 2 (in Applicants' remarks of August 31, 2009). Mullner et al., being directed to water content ranging from 5-99 wt %, do not suggest selecting the narrow range required by the claims, nor provide a reasonable expectation of success for improving the decomposition rate by selecting a water content in this range as shown by Table 2, reproduced from the specification. (3) Table 1 of the new declaration of Yuuiti Tsuda shows that selection of a hydration range between 20% and 80% surprisingly provides superior hydrolysis

as well as increased yield of hydrolysate. This result is surprising because the prior art did not suggest that the degree of hydration was linked to superior hydrolysis, nor suggest optimizing the degree of hydration of the feather raw material to the range 20% to 80%. This increase in decomposition rate reflects the superior hydrolysis of the hydrated raw material and this superior hydrolysis provides a greater yield of keratin. Applicant's arguments have been fully considered but they are not persuasive.

(1) Reply: It should be noted that Mullner et al. was cited to note that the starting material can be a keratin material having a water content of 5-99 wt %, and not to the protein hydrolysis process that is used. Therefore, regardless of the protein hydrolysis process that is used (i.e. enzymatic hydrolysis or alkaline hydrolysis), it would be reasonable for one of ordinary skill to know that any appropriate keratin material can be used as the starting material for the protein hydrolysis process. Further, Shiojima et al. disclose that the decomposition of keratin can be conducted by various protein hydrolysis processes including by acid, by alkali, by enzyme, and that said keratin can be pretreated (i.e. washing) before the hydrolysis process (col. 22 lines 9-65). Therefore, it would be reasonable for one of ordinary skill to know that the keratin material having a water content of 5-99 wt % of Mullner et al. can be substituted in for the raw keratin starting material of Shiojima et al. since Shiojima et al. disclose that the keratin can be pretreated prior to the alkali hydrolysis process (col. 23 lines 9-33).

(2) Reply: The motivation to substitute in the keratin material having a water content of 5-99 wt % of Mullner et al. is given by Mullner et al. which disclose that using a keratinous substrate having a water content in the range of 5-99 weight % in a protein hydrolysis process can eliminate toxic constituents in the final keratin protein product. Further, the reason or

motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by Applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (motivation question arises in the context of the general problem confronting the inventor rather than the specific problem solved by the invention); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1323, 76 USPQ2d 1662, 1685 (Fed. Cir. 2005) ("One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings."); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) (discussed below); *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991). In this instance, the fact that Appellants use a keratin raw material having a water content of 20-80 wt% in order to achieve superior results does not alter the conclusion that its use in the prior art would be *prima facie* obvious from the purpose disclosed in the Mullner et al. reference (i.e. to eliminate toxic constituents).

Regarding Applicants' assertion that Mullner et al. do not suggest selecting the narrow range of 20-80 wt % from 5-99 wt %, Applicants are reminded that the instant range of 20-80 wt % is within the scope of the 5-99 wt % range of Mullner et al.; therefore, it would be obvious for one of ordinary skill to easily substitute in a keratinous substrate having a water content of 20%, 30%, 40%, 50%, 60%, 70%, or 80% (by weight) because these weight percentages are within the range disclosed by Mullner et al. even if used for a different purpose.

(3) Reply: See the comments under the reply section for (2).

Claims 8, 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nashaat T. Nashed/
Primary Examiner, Art Unit 1656

September 22, 2009

Marsha Tsay
Art Unit 1656